Justification for Abbreviated Presentation Full Safety Review Provided in Briefing Packet

Hizentra Immune Globulin Subcutaneous (Human) (IGSC) 20% Liquid

Pediatric Advisory Committee Meeting, March 14, 2013

Hizentra

Hizentra is a 20% liquid solution of Human Immune Globulin and contains the amino acid Proline as a stabilizer.

Hizentra is indicated for the treatment of primary immunodeficiency. It is administered subcutaneously.

The Pediatric Use section of the label was changed on 2/17/2011 to reflect the safety and effectiveness of Hizentra in individuals 2 to 16 years of age.

Hizentra

Justification for Abbreviated Presentation:

- **Pediatric-focused safety and use review:**
  - **No pediatric deaths in the review period.**
  - **22 serious AEs in the US are consistent with the known safety profile of the drug.**
  - **No new safety concerns were identified.**
  - **Use in pediatrics is low.**
  - **Product includes appropriate labeling related to use in pediatrics.**

Hizentra

Adverse event review 2/17/2011 – 2/16/2012 revealed 22 serious AEs in children <16 years of age in the US

- **Most were infusion site reactions**
- **Other serious events included respiratory tract infections, headache, pain and vomiting**

Hizentra

FDA will continue its standard ongoing safety monitoring.

Does the Committee concur?